Purpose of Meeting:
Review Proposed Section 3 Submission for Chlormequat Chloride by Eastman/Taminco and discussion around data needs

Meeting Date:
July 14, 2016 from 11:00 am – 12:30 pm

Meeting Location:
U.S. EPA
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attendees:
Tony Kish – RD – [HYPERLINK "mailto:kish.tony@epa.gov"]
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David Kossor – Eastman/Taminco – davidkossor@eastman.com
Background (several participants)

Notes:
Text in Black is information that was discussed at the Meeting
Text in *Red Italicized* is information that was discussed after the Meeting

- *EPA granted a waiver for the Immunotoxicity study.*
  - *Tony Kish sent Jessica McLaughlin the HASPOC memo on July 21, 2016.*
- *EPA stated that the Subchronic Inhalation study is required but will allow a waiver based on the current use scenarios with an 11.8% formulation if the label is changed to include a PF5 respirator for pressurized handgun uses in greenhouses.*
  - *Tony Kish sent Jessica McLaughlin the HASPOC memo on July 21, 2016.*

- *EPA granted a waiver for the Acute Neurotoxicity study for the import tolerance petition ONLY as long as Taminco commits to conducting the study for the Section 3 registration.*
    - *The import tolerance petition was submitted on July 20, 2016.*
    - *The estimated completion date of the Acute Neurotoxicity study is January 2017.*
    - *Tony Kish sent Jessica McLaughlin feedback on the waiver for the Acute Neurotoxicity study for the import tolerance on July 21, 2016 via email.*
- EPA stated that Taminco needed to submit a waiver for the Subchronic (90-day) Dog study requirement. A 1 year study is available and may be cited.
    - *Taminco will cite our 1 year dog study to fulfill this requirement.*
- HED cautioned that some of the toxicity studies reviewed from previous registrants were deemed unacceptable. But, since the uses being considered were non-food, they were allowed. In the case of a food-use, they would need Taminco to address those study gaps.
- Taminco confirmed that we will cite the current study at EPA (MRID 46715225) and supplement this study with a new 2006 study to fulfil the Aerobic Soil Metabolism study requirement. Taminco will also include a rationale as to why the newer study is more accurate in the analysis of the metabolites. EFED asked if the newer methodology used in the 2006 study followed the newest analytical methods applying more exhaustive extractions.
    - *Taminco confirmed that the 2006 study used a better extraction method than the Morgenroth study (MRID 46715225). The initial extraction was very similar (i.e. with regard to solvents, mixing ratios, etc.), but in the 2006 study an additional Soxhlet extraction method was used, which is considered an exhaustive extraction method.*
- The EPA will require an Aerobic Aquatic Metabolism study. For the Anaerobic Soil Metabolism and the Anaerobic Aquatic Metabolism studies, only one of the two is required.
    - Taminco is required to submit a formal waiver for the study that will not be completed.
    - Of the Anaerobic Soil Metabolism and the Anaerobic Aquatic Metabolism studies, EPA prefers to see the Anaerobic Aquatic Metabolism study.
- EPA will require a Terrestrial Field Dissipation study for the Section 3 registration. EPA is receptive to reviewing a protocol for a reduced study prior to Taminco conducting the study.
- EPA confirmed that the requirement for Freshwater Invertebrates study has been fulfilled. EPA is unlikely to grant a waiver for the Estuarine and Marine Toxicity studies, as it is required for all similar registrations.
    - *Taminco will initiate an Acute Sheepshead Minnow study and an Acute Mysid Shrimp study to support the Section 3 registration.*
- Fish Early Life Stage study is required. A registrant previously submitted a waiver for this study, which was denied. We can use a Fish Full Life Cycle study for this requirement (850.1500). The MRID numbers listed on the slide were deemed to not be acceptable.
    - *Taminco will conduct a Fathead Minnow Early Life Stage study to fulfil this requirement.*
- EPA is starting registration review of chlormequat chloride. The preliminary work plan will be opening in September 2016. Jordan Page is the PRD Chemical Review Manager assigned to chlormequat chloride.
- Taminco needs to conduct an Avian Acute Oral study on passerine. Taminco also has to conduct an Avian Quail Reproductive study and an Avian Duck Reproductive study.
    - No NOEC is available currently in a submitted Avian Quail Reproduction study.
    - This information will be seen in the registration review problem formulation.

- For bees, Taminco will need the full Tier 1 study set. The current data set includes an Adult Honey Bee Acute Oral study. Additional required data are an Adult Honey Bee Chronic Oral study, a Larvae Honey Bee Acute Oral study, and a Larvae Honey Bee Chronic Oral study.
- In regards to the data requirements for Vegetative Vigor, Taminco has Tier 2 studies.
    - *After looking at the protocol we determined that ten plant species were tested at multiple test concentrations.*
- EPA stated that Taminco has prepared many residue trials and they would be receptive to a request to reduce the number of trials. Taminco does not need processing trials on barley and oats. Processing trials are only required on wheat and the Agency will bridge the data from wheat to barley and oats.
- *EPA stated that Taminco's import tolerance petition for chlormequat chloride did not qualify for the new pilot program because we are submitting residue data from Canada that has not been reviewed by any other regulatory authority.*